

## PATENT COOPERATION TREATY

## PCT



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 01 JUL 2005

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Applicant's or agent's file reference P-INCI-X-04-0271	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. PCT/EP2004/008508	International filing date (day/month/year) 29.07.2004	Priority date (day/month/year) 30.07.2003
International Patent Classification (IPC) or national classification and IPC A61K31/4468, A61K31/454, A61K31/4545, A61K31/4525, C07D211/58, C07D401/12, A61P3/04		
Applicant LABORATORIOS DEL DR. ESTEVE S.A. et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  28.02.2005	Date of completion of this report  30.06.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Telephone No. +49 89 2399- 	

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/008508

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-106 as originally filed

**Claims, Numbers**

1-56 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-56
	No: Claims	
Inventive step (IS)	Yes: Claims	1-56
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-56
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
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International application No.

PCT/EP2004/008508

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The following documents have been cited in the International Search Report:

D1: WO 98/35957 A (BAYER AG (D)) 20 August 1998 (1998-08-20)

D2: US-B-6 399 6311 (PFIZER INC (US)) 4 June 2002 (2002-06-04)

D3: WO 01/09120 A (ORTHO MCNEIL PHARM INC (US)) 8 February 2001 (2001-02-08)

D4: WO 01/07409 A (ASTRAZENECA UK LTD (UK)) 1 February 2001 (2001-02-01)

**Novelty (Article 33(2) PCT)**

The present compounds differ from the structurally closest related prior art compounds in D1 and D3 in that B and R5 do not form a ring together and from the closest examples in D2 and D4 in the phenylamino group.

The present claim set is therefore novel.

**Inventive Step (Article 33(3) PCT)**

D1-D4 disclose NPY5 ligands for the treatment of obesity. D1 can be regarded as the closest prior art.

The problem of the invention was the provision of new NPY5 ligands for the treatment of obesity.

None of the cited documents alone or in combination suggests the present substituent B.

The present claim set is therefore based on an inventive step.

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

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**Re Item VI**

**Certain documents cited**

Reference is made to the following P-documents:

D5: WO 03/084939 A (LABORATORIOS DEL DR. ESTEVE (ES)) 16 October 2003  
(2003-10-16), P-document

The P-document D5 does not disclose any compounds within the present scope nor does it suggest the present substituent B, which is the special technical feature of the invention. Even if it was later found that the claimed priority is not valid, D5 would therefore not change the present assesment of novelty and inventive step.